

October 25, 2004

EA 04-118

Jorge A. Perera
Plant General Manager
Baxter Healthcare Corporation
P. O. Box 1389
State Road 721, Km. 0.3
Aibonito, PR 00705

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES
- \$44,400 - (NRC Augmented Inspection Team Report 03019882/2004002; NRC
Inspection Report 03019882/2004003; and NRC Office of Investigations Report
No. 2-2004-006)

Dear Mr. Perera:

The enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) is being issued to Baxter Healthcare Corporation (Baxter) based on six violations of NRC requirements. The circumstances associated with these violations were reviewed by the NRC during an Augmented Inspection Team (AIT) inspection conducted between April 22, 2004, and June 1, 2004, after a Baxter representative informed the NRC on April 21, 2004, that an event had occurred at the facility. The event involved two individuals (an irradiator operator and assistant) bypassing safety interlocks and entering the irradiator at a time when an irradiator source rack (containing 2,000,000 curies of cobalt-60) was stuck in an unshielded position. After receiving notification of this event, the NRC issued a Confirmatory Action Letter (CAL) on April 22, 2004, as well as a CAL revision on April 27, 2004, which documented your agreement to take a number of actions, including obtaining NRC approval of your plan for recovery of the sources, as well as making notification to the NRC before restarting operations.

The AIT was formed to assess the causes of the April 21, 2004, event. The AIT determined that at the time the two individuals entered the irradiator while the source rack was in an unshielded position, they did so under an unwritten and unreviewed procedure which involved bypassing the irradiator safety interlocks. In addition, licensee personnel did not perform adequate surveys to determine radiation levels prior to entering the irradiator. The radiation levels in the path traversed by the individuals in the interim area of the irradiator, which were at least as high as 1600 rad/hour, were not detected until one of the individuals recognized a high reading on the survey instrument he was carrying. The actual doses to the two individuals who entered the irradiator were within regulatory limits. However, the AIT determined that if the two workers had not identified elevated radiation levels while in the interim area, but had continued on their intended path through the irradiation room, their radiation doses would have been at least 450 rad, a dose that is potentially lethal.

Although the direct cause of the stuck source was a ladder left over the irradiator pool after the individuals worked on switches earlier that day, the AIT concluded that inadequate management oversight of the irradiator personnel, inadequate training, and inadequate maintenance programs allowed a poor working environment to develop at the facility. In this environment, equipment degraded and workers' concern for radiation safety declined, as evidenced by personnel circumventing the safety interlock system without adequate safety controls. Also, after the workers had repeated problems with switches or other malfunctions causing the interlocks to prevent entry over a period of years, they became accustomed to believing that when interlocks prevented entry, it was due to such problems and not due to elevated radiation levels from an unshielded source rack.

After completion of the AIT inspection, the NRC also reviewed the AIT results and identified the six violations which were described in another inspection report. Further, the NRC Office of Investigations (OI) initiated an investigation into this matter to determine whether the irradiator operator deliberately bypassed the safety interlock system and deliberately failed to provide dosimetry to his assistant when they entered the irradiator. OI found that the failure to provide the dosimetry was willful, as noted in the report it issued on June 24, 2004.

The findings of the AIT inspection were forwarded to you on June 29, 2004. The findings of the followup review, as well as a factual summary of the OI investigation, were forwarded to you on July 19, 2004. These findings were discussed during a predecisional enforcement conference held with you on August 2, 2004. The discussion included the apparent violations, their causes, and your corrective actions. You also supplemented your presentation at the conference with a letter to the NRC, dated August 23, 2004.

The six violations related to this event are described in the enclosed Notice. The three most significant violations are described in Section I of the Notice. The first violation set forth in Section I involves the failure to adhere to emergency and abnormal event procedures when the safety interlocks were bypassed even though the irradiator source rack fault indicator was illuminated and the source travel alarm had sounded for an extended period. This occurred on at least three occasions, including when the source rack was stuck in the unshielded position on April 21, 2004. This created the potential for a lethal exposure to radiation for the two individuals who entered the area while the sources were exposed, since, as previously indicated, the individuals passed through an area with a radiation level at least as high as 1600 rads/hour, and were planning to enter an area with much higher radiation levels (as high as 100,000 rads/hour in the irradiator cell).

The bypassing of the interlocks after the source rack fault indicator had illuminated and after the source travel alarm sounded for an extended period (without performing the required tests of radiation levels and source rack position, and without the irradiator manufacturer being contacted for assistance, contrary to the procedures), is a very significant violation. The failure occurred twice on April 21, 2004, and also at a very minimum, on at least one occasion prior to that date since licensee representatives informed the NRC, during the inspections, that they had used this unwritten procedure for many years, but more frequently since the Programmable Logic Controller (PLC) was installed in August 2001.

By bypassing the safety interlocks, a system designed to prevent a serious safety event was rendered inoperable, which created the potential for significant injury and loss of life. This was particularly significant on April 21, 2004, when entry was made to the irradiator while a source

rack was stuck in the unshielded position. Although the two individuals received exposures of 4.4 and 2.8 rem respectively, as already noted, both individuals would have received at least 450 rem exposure had they not recognized the radiation level on the survey instrument they were carrying, and then continued on their intended path. Therefore, this violation has been classified at Severity Level II in accordance with Sections C.2 and C.5 of Supplement VI of the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

The second violation set forth in Section I involved the failure to perform an adequate survey prior to the two individuals entering the irradiator on April 21, 2004. Prior to the entry, the operators did not adequately check the irradiator cell radiation monitor, did not adequately check the radiation levels outside the irradiator facility, and did not adequately do other such surveys as were reasonable to determine that a source rack was stuck in the unshielded position and had not returned to the fully shielded position. This violation is also of very significant concern to the NRC since the two individuals walked through a very high radiation field without knowing that beforehand, thereby creating the potential for a significant injury or loss of life. Therefore, this violation has also been classified at Severity Level II in accordance with Section C.5 of Supplement VI of the Enforcement Policy.

The third violation set forth in Section I of the Notice involved the failure by the irradiator operator to supply his assistant an individual radiation monitoring device when the two individuals entered the irradiator on April 21, 2004, while a source rack was stuck in the unshielded position. Based on the OI investigation, the NRC concluded that this violation was willful. In reaching this conclusion, the NRC considered the facts that: (1) the irradiator operator admitted to OI that he was familiar with the Baxter procedure that requires operators to obtain dosimetry for the assistant if entering the irradiator; and (2) the irradiator operator had assigned dosimetry to the assistant for two previous irradiator entries on the same day. As such, the irradiator operator's failure to provide the monitoring device to the assistant was considered to be in careless disregard of the NRC requirements, and therefore willful within the context of the NRC enforcement policy. Willful violations are a serious concern because the NRC's regulatory program relies, in part, on the care that licensees and their employees take to operate safely and in compliance with requirements. As such, willful violations cannot be tolerated. This willful violation has been classified at Severity Level III in accordance with the Enforcement Policy.

In accordance with the current version of the NRC Enforcement Policy, a base civil penalty in the amount of \$9,600 is considered for a Severity Level II violation and a base civil penalty in the amount of \$6,000 is considered for a Severity Level III violation. Given the very high significance of Violation I.A, each occurrence of the violation is being treated as a separate violation for purposes of determining the civil penalty amount.

Since Violations I.A and I.B were classified at Severity Level II, and since Violation I.C was willful, the NRC considered whether credit was warranted for *Identification and Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for identification is not warranted for any of these violations because they were all identified as a result of an event, and not because of any special self monitoring effort by your management or staff. Further, Violations I.A and I.B were particularly egregious in that they created a substantial potential for significant injury or loss of life. Credit for corrective action is warranted since your actions, once the event occurred, were considered prompt and comprehensive. Those actions, which were described during the AIT, at the

enforcement conference, and in your August 23, 2004, letter to the NRC, included, but were not limited to: (1) revision to procedures for responding to emergency conditions and performing necessary surveys; (2) plans to annually review the standard operating procedures for adequacy; (3) upgrade of the training program and retraining of staff on revised procedures, survey techniques, and dosimetry use; and (4) increased management oversight of the irradiator program, including: (a) monthly reviews of the irradiator department by the Plant General Manager, Manufacturing Director, Radiation Safety Officer (RSO), and the assistant RSO (ARSO); (b) annual internal audits of the irradiator by the Environmental Health and Safety Manager and RSO; and (c) additional periodic audits of the irradiator by the corporate environmental health and safety group as well as by an external consultant.

Accordingly, in order to emphasize the significance of these violations, as well as the importance of implementing your corrective actions in a manner to preclude recurrence of the violations, the NRC proposes to impose a civil penalty in the amount of \$44,400 for the violations set forth in Section I of the Notice. The other three violations identified during the inspection are described in Section II of the enclosed Notice and are classified at Severity Level IV.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you may reference any previous correspondence that is applicable to this case to avoid repetitive submissions. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

If you disagree with the enforcement sanction with respect to Violation I.C, you may request alternative dispute resolution (ADR) with the NRC concerning that violation. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The NRC is currently utilizing ADR during a pilot program for any issues involving willful or deliberate violations. The technique that the NRC has decided to employ during a pilot program which is now in effect is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and the licensee) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Generally, the NRC is willing to discuss the resolution of three potential issues regarding any willful or deliberate violation: (1) whether a violation occurred; (2) the appropriate enforcement action; and (3) the appropriate corrective actions for the violation. Additional information concerning the NRC's pilot program can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The

Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact ICR at (607) 255-1124 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. You may also contact Nick Hilton, Office of Enforcement, at (301) 415-3055 for additional information.

Questions concerning this Notice may be addressed to John D. Kinneman, Chief, Security and Industrial Nuclear Safety Branch, Division of Nuclear Materials Safety. Mr. Kinneman can be reached at telephone number (610) 337-5252.

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 03019882
License No. 52-21175-01

Enclosures:

1. Notice of Violation and Proposed
Imposition of Civil Penalties
2. NUREG/BR-0254 Payment Methods (Licensee only)

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Commonwealth of Puerto Rico

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R. Tadesse, OEDO

C. Miller, OEDO

Enforcement Coordinators

RII, RIII, RIV

S. Gagner, OPA

H. Bell, OIG

P. Lohaus, STP

G. Caputo, OI

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NAME		DHolody (DJH)	GPangburn (JDK for)	EWilson (EPW)	KFarrar (KLF)
DATE		09/29/04	09/29/04	09/29/04	09/30/04

OFFICE	NMSS	OGC	OE	RI/RA
NAME	Linda Gersey for Charles Miller	J. McGurren for Brad Jones	FCongel *	SCollins (SJC)
DATE	10/18/04	10/18/04		10/25/04

S. Merchant notified RI that J. Luehman concurred for F. Congel 10/18/04.

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Baxter Healthcare Corporation
Aibonito, PR

Docket No. 03019882
License No. 52-21175-01
EA 04-118

As a result of an NRC Augmented Inspection Team Inspection (AIT) and followup review of the AIT inspection conducted at Baxter Healthcare Corporation Inc. (PMK) between April 22, 2004, and June 1, 2004, as well as an investigation by the NRC Office of Investigations (OI), the report of which was issued on June 24, 2004, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the NRC proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282 and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. VIOLATIONS ASSESSED A CIVIL PENALTY

- A. 10 CFR 36.53(b)(1) requires, in part, that the licensee have and follow emergency and abnormal event procedures, appropriate for the irradiator type, for sources stuck in the unshielded position.

Condition 17 of License No. 52-21175-01 requires that the licensee conduct its program in accordance with the commitments described in letters listed therein, including a letter dated September 12, 1994, containing the "Irradiator Operating Procedures" and the "Irradiator Emergency and Abnormal Event Procedures."

The Irradiator Operating Procedure for start-up of the irradiator requires, in part, in Section 4.1.A.3, that if a source rack fault indicator is illuminated, the operator is to refer to the appropriate emergency procedure.

The Irradiator Emergency and Abnormal Event Procedures includes the "Stuck Source Rack Procedure", which requires, in Section 4.1, that the procedure be implemented if the source travel alarm sounded for more than the preset time or if the source rack fault indicator on the console illuminated, indicating the source rack may be stuck. Section 4.1 also requires several tests of radiation levels and position of the source rack, and contacting the irradiator manufacturer for assistance.

Contrary to the above, on two occasions on April 21, 2004, and on at least one occasion prior to that date, the licensee did not follow the emergency and abnormal event procedures after the source rack fault indicator on the console was illuminated and the source travel alarm sounded for an extended period. Specifically, in each case, the licensee bypassed safety interlocks and personnel gained entry into the interim area of the irradiator facility without the required tests of radiation levels and position of the source rack being done, and without

the irradiator manufacturer being contacted for assistance. On one of those occasions on April 21, 2004, a source rack (containing 2,000,000 curies of cobalt-60) was actually stuck in the unshielded position, thereby creating the potential for a lethal radiation exposure to the individuals who entered the area.

This is a Severity Level II violation (Supplements VI)
Civil Penalty -\$28,800 (\$9,600 for each of the three stated occurrences)

- B. 10 CFR 20.1501(a)(2) requires, in part, that each licensee make surveys that are reasonable to evaluate the magnitude and extent of radiation levels and potential radiation hazards.

Contrary to the above, on April 21, 2004, while an irradiator source rack (containing 2,000,000 curies of cobalt-60) was stuck in the unshielded position, two irradiator operators entered the interim area of the irradiator, after bypassing safety interlocks, without performing a survey that was reasonable to evaluate the extent of radiation levels and the potential radiation hazards. Specifically, prior to the entry, the operators did not check the irradiator cell radiation monitor, did not check the radiation levels outside the irradiator facility, nor did they perform other such surveys reasonable to determine that the source rack was stuck in the unshielded position, had not returned to the fully shielded position, and had led to radiation levels inside the interim area of irradiator cell at least as high as 1600 rads/hour.

This is a Severity Level II violation (Supplement IV and VI).
Civil Penalty -\$9,600

- C. 10 CFR 36.55(a) requires, in part, that irradiator operators wear a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. 10 CFR 36.55(b) requires, in part, that other individuals who enter the irradiator wear a dosimeter, which may be a pocket dosimeter.

Condition 17 of License No. 52-21175-01 requires that the licensee conduct its program in accordance with the commitments described in letters listed therein, including a letter dated February 5, 1995, which includes the "Irradiator Operating Procedure" and which requires all irradiator operators to wear an assigned dosimeter and any visitor entering the irradiator to wear a pocket dosimeter.

Contrary to the above, on April 21, 2004, the licensee did not supply and require the use of an individual radiation monitoring device by an individual who entered the irradiator. Specifically, an individual accompanied the irradiator operator into the interim area of the irradiator (after the safety interlocks were bypassed to gain entry), and walked through a radiation field at least as high as 1600 rad/hour, and the individual did not have a personnel monitoring dosimeter or a pocket dosimeter during the entry.

This is a Severity Level III violation (Supplement IV).
Civil Penalty - \$6,000

II. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

- A. 10 CFR 36.51(d) requires the licensee to conduct safety reviews for irradiator operators annually, and the annual safety review shall include, to the extent possible, a number of topics including changes in operating and emergency procedures since the last review, as well as a drill to practice an emergency or abnormal event procedure. A brief written test shall also be given to each operator regarding the information.

Contrary to the above,

1. between February 1, 2000, and April 21, 2004, the licensee did not conduct safety reviews for certain irradiator operators annually. Specifically,
 - a. between February 1, 2000, and April 21, 2004, the Radiation Safety Officer and an Alternate Radiation Safety Officer, both of whom are irradiator operators, did not have a safety review;
 - b. between February 14, 2000, and February 24, 2004, another Alternate Radiation Safety Officer, who also is an irradiator operator, did not have a safety review.
2. between April 15, 1999, and August 20, 2003, the licensee did not conduct any drills to practice an emergency or abnormal event procedure. In addition, the drills practiced on August 26, 2003, August 20, 2003, and April 15, 1999, and August 14, 1998, used the same event (an alarm of the exit maze monitor) and did not test any of the other nine types of emergency or abnormal events required in their emergency procedures.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 36.51(e) requires, in part, that the licensee evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed, and the licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

Contrary to the above,

1. prior to April 21, 2004, the licensee did not evaluate the safety performance of two irradiator operators, namely the Radiation Safety Officer and an Alternate Radiation Safety Officer, and

2. between July 16, 1999, and April 21, 2004, the licensee did not evaluate the safety performance of another irradiator operator who was also an Alternate Radiation Safety Officer.

This is a Severity Level IV violation (Supplement VI).

- C. Condition 17 of License No. 52-21175-01 requires that the licensee conduct the licensed program in accordance with commitments in the application dated July 22, 1993. One of the commitments states that they will administer the same "Operator Qualification" examination annually to each operator.

Contrary to the above, between November 1999, and April 2004, the "Operator Qualification" examination was either not administered, or not adequately administered annually to certain irradiator operators. Specifically,

1. one ARSO who is an operator did not take this examination in 2002 or 2003;
2. another ARSO who is an operator last took this examination on October 13, 1999;
3. the RSO, who is an operator, last took this examination on March 28, 2000; however, the RSO's examination was not graded or reviewed by anyone;
4. some wrong answers on other examinations were not marked as incorrect and were not corrected or discussed with the person who took the exam;
5. this examination is the exact same test each year, and does not cover new or alternate questions.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Baxter Healthcare Corporation is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation, EA 04-118" and should include for each alleged violation:

(1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil Penalties proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil Penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil Penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation, EA 03-036" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the Penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.C.2 of the Enforcement Policy should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: F. Congel, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 25th day of October 2004